

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY, INC.) MDL No. 2419
PRODUCTS LIABILITY LITIGATION) Dkt. No. 1:13-md-2419-FDS

This Document Relates to:)

Barger, et al. v. Ameridose, LLC et al.) Dkt. No. 1:13-cv-12619-FDS

AFFIDAVIT OF JOHN W. CULCLASURE, M.D.

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

Comes John W. Culclasure, M.D., after first being duly sworn, and states as follows:

1. I am over 18 years of age, have personal knowledge of the facts contained herein, and am competent to testify to same.

2. I am currently the Medical Director at Saint Thomas Outpatient Neurosurgical Center, LLC, and I was the Medical Director at Saint Thomas Outpatient Neurosurgical Center, LLC, at all times relevant hereto.

3. I administered epidural steroid injections to Plaintiffs Vickie Barger, Lisa Maddox, Wayne McWhorter, Samuel Groves, Betty Smiley, John Edward Jones, Angela May, and Gary Wayne Waddey as part of my medical treatment and health care of the patients.

4. On September 7, 2012, I performed a medial branch block injection on Plaintiff Claudia Ellis. Ms. Ellis received an injection of 0.5 ml of 1:1 mix of pf .75% Bupivacaine + pf 4% Lidocaine.

5. Ms. Ellis did not receive New England Compounding Center preservative-free methylprednisolone acetate from one of the three recalled lots.

6. During an epidural steroid injection, the patient's vital signs are monitored. The patient is placed prone and, utilizing aseptic technique, the injection site is prepped. I use C-arm fluoroscopy to identify the site for needle placement. I then direct the needle to the target area and confirm the needle location utilizing contrast dye and the C-arm fluoroscopy. Once needle location is confirmed, I administer the steroid and monitor the patient's tolerance.

7. The procedure as I have described it for an epidural steroid injection complies with the accepted standard of care for those procedures in this community. I am familiar with that standard of care based on my education, training, and experience, and particularly on my experience practicing as a physician in the Nashville medical community performing such injections in 2012.

8. A different physician administered epidural steroid injections to Plaintiffs Peggy Sumner, Anthony Clay Morris, Betty Smiley, Shenia Altom, and Virginia Swann at Saint Thomas Outpatient Neurosurgical Center, LLC. This was done as part of the patient's care at Saint Thomas Outpatient Neurosurgical Center, LLC.

9. At Saint Thomas Outpatient Neurosurgical Center, LLC, only licensed physicians perform epidural steroid injections.

10. At Saint Thomas Outpatient Neurosurgical Center, LLC, spinal epidural steroid injections are performed on patients following a diagnosis of, and as treatment and care for, pain related to spinal nerves.

11. In June of 2011, I, along with Debra Schamberg, R.N., made the decision to purchase preservative-free methylprednisolone acetate from the New England Compounding Center for Saint Thomas Outpatient Neurosurgical Center, LLC.

12. I am currently a licensed physician, and I was licensed as a physician during all times relevant hereto.

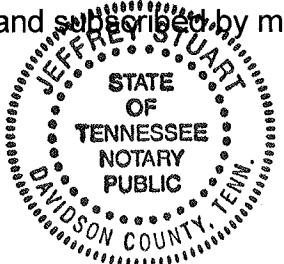
13. Saint Thomas Outpatient Neurosurgical Center, LLC, is currently licensed as an ambulatory surgery center, and it was licensed as an ambulatory surgery center during all times relevant hereto.

14. Saint Thomas Outpatient Neurosurgical Center, LLC, through the health care providers working there, provides health care services to patients, including the provision of care to the Plaintiffs in this case.

[Signature]
(Signature of Affiant)

Sworn to and subscribed by me on this 29 day of November, 2013.

[Signature]
(Notary Public)



My Commission Expires May 20, 2014